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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/612,832 | 07/01/2003 | Harald Stein | 086035-000000US | 3864 |

20350 7590 02/24/2005

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| EXAMINER | |
|---|---|
| YAO, LEI | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/612,832 | STEIN ET AL. | |
| | Examiner | Art Unit | |
| | Lei Yao, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☐ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-30* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18 In part and 29-30 in part, drawn to a reagent for diagnosis and/or therapy, cells producing said reagent, pharmaceutical composition and kits comprising said reagent, wherein the reagent enter into interactions with a cell bound or soluble molecule, classified in class 530, subclass 387.1.

II. Claims 1-18 in part and 29-30 in part, drawn to a reagent for diagnosis and/or therapy, cells producing said reagent, pharmaceutical composition and kits comprising said reagent, wherein the reagent enter into interactions with a nucleic acid encoding a cell bound or soluble molecule, classified in class 536, subclass 23.1

III. Claims 19-20, drawn to a method for diagnosis of tumor or inflammatory disease comprising contacting a sample from patient to the reagent of Group I, classified in class 424, subclass 184.1

IV. Claims 19-20, drawn to a method for diagnosis of tumor or inflammatory disease comprising contacting a sample from patient to the reagent of Group II, classified in class 424, subclass 184.1.

V. Claims 21-27*, drawn to a method for treating a patient having tumors, inflammatory allergic, autoimmune diseases comprising administering the reagent of Group I , classified in class 424, subclass 184.1 and 130.1.

VI. Claims 21-27*, drawn to a method for treating a patient having tumors, inflammatory allergic, autoimmune diseases comprising administering the reagent of Group II , classified in class 424, subclass 184.1 and 130.1.

VII. Claim 28, drawn to a method of making the composition for the suppression or avoidance of rejection reaction and/or graft-versus-host reaction in the transplantation of organs, bone marrow, or stem cells, unclassified.

Group I and II are patentably distinct product. They are distinct in structure, function and usage. Searching the inventions of Group I and Group II would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications and technical literature search for the products in Group I and Group III are not coextensive.

Inventions Group I and Groups III or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the reagent of Group I can be used to detect protein in the sera or on the cells in vitro, as opposed to being used as a reagent for diagnosis or treatment in vivo.

Searching the inventions of Groups I and Group III or V together would impose serious search burden. The inventions of Groups I and III or V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the reagent and the method of diagnosing tumor of inflammatory disease using a reagent are not coextensive. Moreover, even if the product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps.

Inventions Group II and Groups IV or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the reagent of Group I can be used to detect protein in the sera or on the cells in vitro, as opposed to being used as a reagent for diagnosis or treatment in vivo.

Searching the inventions of Group II and Groups IV or VI together would impose serious search burden. The inventions of Group II and Groups IV or VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the reagent and the method of diagnosing tumor of inflammatory disease using a reagent are not coextensive. Moreover, even if the product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps.

The methods of Group III, IV, V, VI, and VII differ in the method objectives, method steps and parameters and in the reagents used. The instant specification does not disclose these methods would be used together. Group III and IV are directed to diagnosing tumor of inflammatory disease in vivo using different reagents, Group V and VI are directed to a method of treating a tumor, inflammatory or autoimmune disease using different reagents, whereas Group VII is directed to method of making the composition for the suppression or avoidance of rejection reaction and/or graft-versus-host reaction

The methods of diagnosing of tumor or inflammatory disease (Group II), and the method of treating a tumor, inflammatory or autoimmune disease, and a method of making the composition for the suppression or avoidance of rejection reaction and/or graft-versus-host reaction have a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis of disease (Group III and IV) may differ significantly from treating disease (Group V and VI), and making the composition (VII) for each of the materials and steps. Therefore, each method is divergent in materials and steps. For these reasons the Inventions Group III, IV, V, VI, and VII are patentably distinct.

***Election of species***

The application including the following distinct species groups:

A 1) antibodies, antibody fragment, chimerized antibodies, humnaise antibodies, and single chain(Sv) Fv fragments

2) sc-T-cells receptor (TCR) fragment, hybrid scFv/scTCR garments.

3) RNA or DNA aptamers and RNA or DNA spiegelmers.

B.

1)Toxin

2) enzyme

3) radioactive isotopes

4) photactivatable compounds

C.

1)Tumor

2) inflammatory

3) inflammatory allergic

4) autoimmune diseases.

In the event that applicant elects invention I –VI applicant is required under 35 U.S.C. 121 to elect a single disclosed species from A and B for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 3 is generic.

In the event that applicant elects invention III- VI, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from C for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

1. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

2. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or

clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

6. In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

7. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

Karen A. Canella

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PRIMARY EXAMINER